

## Outcome of wide local excision with and without corticosteroid therapy in management of idiopathic granulomatous mastitis

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### ABSTRACT

**Introduction:** Idiopathic granulomatous mastitis is considered as one of the rare benign breast disease. It can be misdiagnosed as breast carcinoma both clinically and radiologically. Tissue biopsy and histopathological assessment is the gold standard for diagnosis. Proper management of Idiopathic granulomatous mastitis is still controversial. In our study, we aimed to evaluate the addition of corticosteroid therapy to surgical excision in management of idiopathic granulomatous mastitis. **Patients and Methods:** This is a comparative study which was conducted at Ain-Shams University Hospital's breast clinic on patients with idiopathic granulomatous mastitis from August 2015 till September 2018. Thirty patients were divided into 2 groups. Group (A) consistent of participants who received surgical management only. Group (B) includes patients who received corticosteroid therapy according to the severity of the cases then surgical Excision was done for the residual lesion. Follow up of the cases was done up to 1-2 years to document the recurrence rate and to assess the cosmetic outcome of both groups. Informed consent was obtained from all the cases included in the study. **Results:** The mean age of the affected women was 38.80 and 33.13 in group (A) and group (B), respectively and it wasn't statistically different (p value = 0.099). The most common presenting symptom was a palpable mass in the breast (66.7% and 93.3%) in group (A) and group (B) respectively. Recurrence rate was higher in group (A) (40%) with no recurrence documented in group (B) however 2 cases were omitted from the study due to steroid noncompliance and complications. Cosmetic outcome was found to be excellent in 76.9% of group (B) and good in 53.3% of group (A). **Conclusion:** Systemic steroid with surgical resection is recommended as a treatment strategy for IGM as it shows less recurrence rate and less post- surgical scarring. Further larger studies are recommended for better awareness of IGM to improve its management in our country.

**Keywords:** granulomatous mastitis, breast, steroid



## 1. INTRODUCTION

Granulomatous mastitis (GM) is an entity represents granulomatous inflammation of the breast that is idiopathic or occurs in association with diseases such as tuberculosis (TB), sarcoidosis, and parasitic infection. It was first described by Kessler and Wolloch in 1972 (Hur et al., 2013). The prevalence of Granulomatous Mastitis is generally reported at less than 1% worldwide among women presenting with breast problems (D'Alfonso et al., 2015). IGM is characterized by chronic non necrotizing granulomatous lobulitis of unknown etiology. It often misdiagnosed as breast carcinoma clinically and radiologically (Bouton et al., 2015). Clinical information and radiographic findings of IGM may help in the differentiation between IGM and breast carcinoma, however, histopathological confirmation is still required for proper diagnosis and treatment of the lesion (Yildiz et al., 2015).

Granulomatous mastitis treatment is complicated and needs patience and long-term follow-up. The treatment choices include corticosteroids, antibiotics, abscess drainage, wide surgical resection, and even mastectomy. In specific infections, the treatment is specific to the disease, although in idiopathic granulomatous lobulitis systemic steroid is proven to be useful. However, the optimal treatment of patients is uncertain. Freeman et al., (2017) were the first to recommend the use of corticosteroids for the treatment of granulomatous mastitis. Steroid treatment can be administered after excision for complicated and resistant cases, or those patients who have had an incisional biopsy only and it may also be wise to give steroids in cases with large irresectable lesions before surgery.

## 2. PATIENTS AND METHODS

This is a comparative study was conducted on patients presenting to Ain-Shams University Hospital's breast clinic with idiopathic granulomatous mastitis from August 2015 till September 2018 to evaluate the addition of corticosteroid therapy to surgical excision in management of idiopathic granulomatous mastitis. Thirty patients were included in the study divided into 2 groups. Group (A) is the surgery only group which includes patients who underwent surgical management only. Group (B) is the combined management group which includes patients who was received corticosteroid therapy according to the severity of the cases (size of the granulomatous lesion, sinus formation) then surgical excision was done for the residual lesion. A clinical history was taken and a proper physical examination was performed. Exclusion criteria were Patients diagnosed with specific granulomatous mastitis such as TB, sarcoidosis, Wegener's granulomatosis and Patients whom final diagnosis was breast cancer. Patients with Known medical comorbidities such as diabetes or pre-diabetic state were excluded from the steroid group as well.

Breast ultrasonography (US), mammography, and magnetic resonance imaging (MRI) were used depending on the age and clinical condition of the patient. Ultrasonography (US) was done for all the patients included in our study in both groups. Mammographic examination was combined with ultrasonography examination in some cases and performed in craniocaudal and mediolateral oblique positions. 7 patients and 6 patients were examined with mammography (MMG) from group (A) and group (B) respectively. Only 2 patients were indicated for magnetic resonance imaging (MRI) one patient for each group for inadequate assessment by MMG. Core needle biopsy was done in 9 patients and 13 patients in group (A) and group (B) respectively. Culture and sensitivity was done in patients who presented with collection or discharging sinuses those was 5 patients in group (A) and 9 patients in group (B). Follow up of all cases up to 1-2 years was done to document the recurrence rate and compare the cosmetic outcome of both groups. All patients sharing in the study was informed about the management they will have, its possible sequelae, and its complication with a written consent.

Statistical analysis was performed using SPSS (IBM SPSS) version 23. Comparisons between groups were made using Chi-square test and/or Fisher exact test and Independent t-test. The confidence interval was set to 95% and the margin of error accepted was set to 5% so a p value < 0.05 was considered as significant.

## 3. RESULTS

### Clinical characteristics

The clinical features of all patients with IGM are shown in table 1 and 2. The mean age of the affected women was 38.80 (range: 29 – 44) and 33.13 (range: 25 – 40) in the surgery-only (A) group and the combined management (B) group, respectively and it wasn't statistically different between the 2 groups (p value = 0.099). Nearly all patients has a history of lactation in the past 5 years with mean interval before diagnosis of 2.43 year (range: 1– 5), and 2.51year (rang: 1.2 – 4) at group (A) and group (B) respectively. 12 patients have a history of OCP use in both groups (table 1).

None of the patients have a history of TB and only 1 patient in group (B) has a family history of breast cancer. According to the past medical history (table 2) in group (A), only 1 patient was diabetic and 1 patient was diagnosed with hyperthyroidism 1 year

before presentation. In group (B) only one patient has history of bronchial asthma and skin allergy and another patient has history of vitiligo. Clinical presentation were shown in table 3.

**Table 1** Clinical characteristics of the study patients

		Group (A)	Group (B)	Test value	P-value	Sig.
		No. = 15	No. = 15			
Age	Mean±SD	38.80 ± 4.65	33.13 ± 3.87	1.708•	0.099	NS
	Range	29 – 44	25 – 40			
Last lactation by years	Mean±SD	2.43 ± 1.13	2.51 ± 0.84	0.220•	0.828	NS
	Range	1– 5	1.2 – 4			
History of OCP	No	9 (60.0%)	9 (60.0%)	0.000	1.000	NS
	Yes	6 (40.0%)	6 (40.0%)			
History of Pregnancy in last 5 years	No	3 (20.0%)	0 (0.0%)	3.333	0.068	NS
	Yes	12 (80.0%)	15 (100.0%)			

**Table 2** Clinical characteristics of the study patients

		Group (A)		Group (B)		Test value*	P-value	Sig.
		No.	%	No.	%			
History of TB	No	15	100.0%	15	100.0%	NA	NA	NA
Family History of Breast cancer	No	15	100.0%	14	93.3%	1.034	0.309	NS
	Yes	0	0.0%	1	6.7%			
CHR disease	No	13 (86.7%)		13 (86.7%)		4.000*	0.406	NS
	Hyperthyroidism	1 (6.7%)		0 (0.0%)				
	DM	1 (6.7%)		0 (0.0%)				
	Vitiligo	0 (0.0%)		1 (6.7%)				
	BA ,skin allergy	0 (0.0%)		1 (6.7%)				

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS) \*:Chi-square test; \*: Independent t-test

**Table 3** Clinical presentation

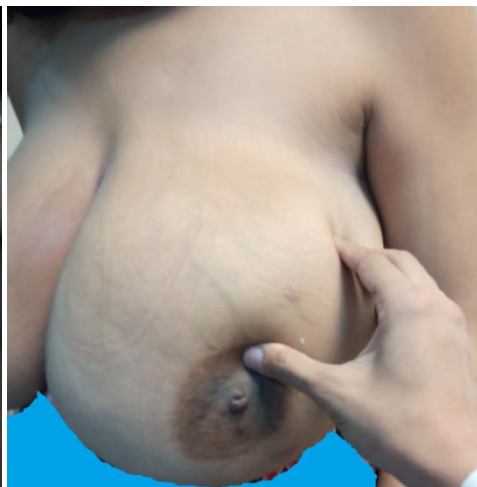
		Group (A)		Group (B)		Test value*	P-value	Sig.
		No.	%	No.	%			
Side	Left	9	60.0%	7	46.7%	1.327	0.515	NS
	Right	6	40.0%	7	46.7%			
	Bilateral	0	0.0%	1	6.7%			
Mass	No	5	33.3%	1	6.7%	3.333	0.068	NS
	Yes	10	66.7%	14	93.3%			
Abscess	No	10	66.7%	10	66.7%	0.000	1.000	NS
	Yes	5	33.3%	5	33.3%			
Sinus	No	15	100.0%	11	73.3%	4.615	0.032	S
	Yes	0	0.0%	4	26.7%			
Skin changes(erythema, swelling)	No	11	73.3%	9	60.0%	2.200	0.333	NS
	Erythema	4	26.7%	4	26.7%			
	Nipple discharge	0	0.0%	2	13.3%			
Associated symptoms	No	14 (93.3%)		11 (73.3%)		2.360*	0.307	NS
	Skin rash	1 (6.7%)		3 (20.0%)				
	Leg Erythema	0 (0.0%)		1 (6.7%)				

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS) \*:Chi-square test

There are 29 patients presented by a unilateral breast IGM and one patient in group (B) was presented with bilateral breast IGM, 9 Patient and 7 patients presented with left side IGM in group (A) and group (B) respectively as well as the right side IGM was 6 Patient and 7 patient in group (A) and group (B) respectively. The most common presenting symptom was a palpable mass in the breast (66.7% and 93.3%) in group (A) and group (B) respectively (Figure 2). The other associated sings includes abscess formation (Figure 1) which was found in 5 patient in each group (33.3%) and Erythema which was found in 4 patients in each group (26.7%). Nipple discharge was found in 2 patients in group (B) and skin sinus was found in 4 patients in group (B) as well. There were extramamary associated symptoms such as skin rash in 1 patient and 3 patients in group (A) and group (B) respectively. One patient in group (B) was presented with leg erythema as an associated extramamary symptom.



**Figure 1** Abscess formation



**Figure 2** granulomatous Mass

### Radiological assessment

The radiological assessment of the lesion according to BIRADS classification was documented. BIRADS 4 category was noted in 6 patients and 4 patients in group (A) and (B) respectively, BIRADS 4a category was noted in 3 and 4 patient in group (A) and group (B) respectively. Only one patient in group (B) was categorized as BIRADS 4b. Benign breast lesions categorized BIRADS 3 was found in 6 patients in each group. The size of the lesions in group (B) was larger than group (A), about 69.2% of lesions was 2-5 cm and about 23.1% was larger than 5 cm.

Sonographic examination show ill-defined hypoechoic lesion associated with interstitial edema in 10 patients from group (A) and 14 patients from group (B), fluid collection was found in group (A) in 5 patients 1 patient from group (B). Four cases from group (B) was found to have mass and fluid collection simultaneously. Mammographic examination varies from an ill-defined mass in most of cases and architectural distortion in 3 patients only. MRI was performed showing ring-like abscess formation (figure 3).



**Figure 3** MRI finding in IGM



### Histopathology Evaluation

Preoperative Core needle biopsy was done in 9 patients and 13 patients in group (A) and group (B) respectively. Postoperative tissue diagnosis was all nonspecific granulomatous mastitis in all cases. Culture and sensitivity was done in patients who presented with collection or discharging sinuses those was 5 patients in group (A) and 9 patients in group (B) (Figure 4).



**Figure 4** Preoperative culture sample collection

Intraoperative culture sample collection

### Treatment

In group (A), wide excision was performed in all patients except 5 patients underwent incision and drainage as they were presented with abscess formation. Patients in group (B) received prednisolone daily with dose ranging from 30-60 mg per day for a mean duration of 2.10 months with tapering of the dose gradually based on the clinical and radiological response. The minimum duration of steroid was for 1 month and the longest steroid period was 3 months and only 2 patients was omitted from the study due to non-compliance for steroids and the other one was for developing of steroids complications. Regarding the surgical management (Table 4) in group (B), 9 patients underwent wide excision of the mass and 4 patients were treated by wide excision and major duct excision for associated nipple discharge (figure 5).



**Figure 5** Wide excision of a residual mass + MDE 1 week post-operative

**Table 4** Surgical intervention

Surgical intervention		Group (A) No. = 15	Group (B) No. = 15	Test value	P-value	Sig.
Excision	No	5 (33.3%)	4 (30.8%)			
	Yes	10 (66.7%)	9 (69.2%)	0.021*	0.885	NS

excision + MDE	No	--	9 (69.2%)	5.275*	0.022	S
	Yes	--	4 (30.8%)			
Incision and drainage	No	10 (66.7%)	13 (100.0%)	5.275*	0.022	S
	Yes	5 (33.3%)	0 (0.0%)			
Mastectomy	No	15 (100.0%)	13 (100.0%)			

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)

\*:Chi-square test

\*: Two patients (13.3%) have been omitted from the study

### Follow-up

Follow-up was ranging from 1 to 2 years. Follow-up was concerned about the recurrence and the cosmetic outcome. Recurrence developed in 6 (40%) patients in the surgery only group (A), whereas there was no recurrence in the combined management group (B) (p = 0.01) (table 5). the patients who develop recurrence were mainly who underwent incision and drainage only as a first management. The disease free interval was ranging from 1 – 3 months, abscess was developed in 2 cases and sinus formation was developed in 3 cases while only one patient developed a recurrent mass at the operative bed (Figure 6).



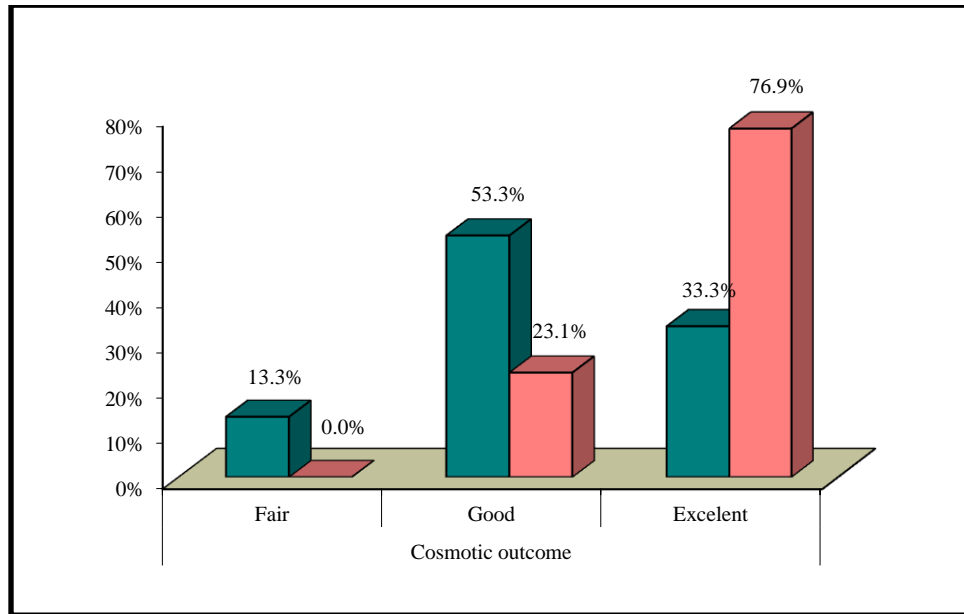
**Figure 6** Recurrent mass after incision and drainage

Recurrence as sinus after excision biopsy

**Table 5** Recurrence

Recurrence		Group (A) No. = 15	Group (B) No. = 13*	Test value	P-value	Sig.
Recurrence	No	9 (60.0%)	13 (100.0%)			
	Yes	6 (40.0%)	0 (0.0%)	6.618*	0.010	S
Time interval of recurrence (months)	Mean±SD	2.08 ± 0.80	-			
	Range	1 – 3	-			
Picture	Sinus	3 (50.0%)	-			
	Abscesses	2 (33.3%)	-			
	MASS	1 (16.7%)	-			

Cosmetic outcome was excellent in 76.9% of group (B) and good in 53.3% of group (A) as the resected volume in group (B) was less than in group (A) (figure 7 & 8).



**Figure 7** cosmetic out come



**Figure 8** Post excision bad cosmetic result

Post excision good cosmetic result

#### 4. DISCUSSION

Granulomatous Mastitis was first described by Kessler and Wolloch in 1972, but Going in 1987 recommended the term “idiopathic granulomatous lobular mastitis (IGLM)” to be used as a more specific term than the generic one of granulomatous mastitis (Going et al., 1987). IGM is an inflammatory breast disease mostly seen in females at a reproductive age (Özel et al., 2012). In our study, all of patients were at reproductive age and all patients were parous, about 90% has history of pregnancy in the last 5 year and 40% of patients have a history of OCP use in both group. The etiology of IGLM is still unclear, but many authors suggest factors as local chemical irritants, undetected viruses, mycotic infection or bacterial micro-organisms, diabetes mellitus, smoking,  $\alpha_1$  antitrypsin deficiency, autoimmune reactions, hyperprolactinemia or even lactation itself, may be involved in the pathogenesis of IGLM (Aziz et al., 2003). IGM presents most commonly with a painful, firm, tender, and ill-defined mass in the breast and unilateral. The lesions may be located in any quadrant of the breast (Patel et al., 2009). IGM is mainly inflammatory process so it can cause skin thickening, sinus and abscess formation, enlarged axillary lymph nodes and nipple retraction which may be clinically mistaken for breast carcinoma (Akcan et al., 2006).

In our study the most common presenting symptom was a palpable mass in the breast and abscess formation which is compatible with most of the studies. Erythema was found in 4 patients in each group (26.7%) and skin sinus was found in 4 patients in group (B) as well. As many studies stated that some cases of IGM may present with concurrent periductal mastitis, nipple discharge was found in 2 patients in group (B). Although IGM mimics breast cancer radiologically, mammography (MG) and ultrasonography (US) can be used to rule out malignancy rather than to provide a differential diagnosis of IGM. A focal asymmetrical density on MG and large heterogeneous hypo echogenicity with internal hypoechoic tubular lesions on US should alert physicians to the possibility of IGM. If there are no significant pathological findings on MG or US, MRI should be considered

for the diagnosis. A focal homogeneous enhancing mass with irregular borders and parenchymal distortion can be seen on MRI, but all three imaging modalities have a limited role in distinguishing IGM from breast cancer (Mizrakli et al., 2015).

Two patients in our study was diagnosed by MRI as one of them has highly dense breast and the other one was positive family history of breast cancer so exclusion of malignancy was critical in such case. The pathological-finding approach is recognized as the gold standard for IGM diagnosis, characterized by non-caseating granulomas concentrated in lobules. Microscopically, the granulomas contain Langhans giant cells, epithelioid histiocytes, and are associated with lymphocytes and plasma cells. Neutrophilic micro abscesses may also be seen. In the newly known cystic neutrophilic granulomatous mastitis, cystic vacuoles are often present within the granulomas and are lined by neutrophils. Gram-positive coryneform bacilli may be present within the cysts. Therefore, pathological analysis is strictly recommended to exclude malignancy (Zhou et al., 2020).

Surgical treatment was the mainstream of treatment before 1980, and is still preferred by many experts nowadays (Larsen et al., 2009). However, the risk of recurrence has limited its application, and multiple surgeries may be required to achieve complete remission. Furthermore, negative-margin surgery affects patients with inevitable side-effects such as cosmetic issues. As suggested by Neel et al., (2013), the first-line surgical therapy did not reduce the incidence of relapse in a long-term follow-up; 80% of the GLM patients relapsed after surgical treatment, and unsightly scars tended to be more frequent among women who had undergone surgery. Our results were compatible with that and surgical management only shows recurrence in 40% of cases. Steroid role in management of IGM was first described by De Hertogh et al. in (1980), it has demonstrated successful results in the treatment of IGM in both earlier case studies and subsequent studies involving many patients (Erozgen et al., 2010).

Steroids was used at a dose of 60 mg/day initially however recently started to be used at lower doses because of its side effect, and successful results have been reported for concentrations of 25.0 mg/day and 0.8 mg/kg/day (Tuli et al., 2007). However, the optimal dose and duration of steroid administration has not been established. Steroids are known to cause side effects related to almost all systems (Peppia et al., 2011). In our study we used steroids dose ranging from 30 to 60 mg per day and steroid complication such as steroid-induced diabetes and hypertension was documented in one case and was omitted from the study. Tapering of the dose was done according to the response of each patient separately and most of cases were kept on low dose steroids (10 mg /day) till the operation and postoperative to improve the healing process and to decrease wound gapping and sinus formation.

Other studies have indicated better outcomes with co-administration of oral steroid together with topical steroids for cutaneous diseases. Steroid alone may be the main treatment modality in cases without abscess or infection (Altintoprak et al., 2015). Some authors recommended reducing the size for complicated and resistant cases or diffuse lesions before excision (Akcan et al., 2006). In our study there was marked reduction of the mass size in the combined management group which facilitate better excision of the residual lesion and so better cosmetic outcome. Oran et al., (2013), reported that steroid therapy group and surgery group showed comparable treatment outcome in view of recurrence (20% versus 16.7%, respectively). Rather, Akahane et al., (2013) reported no recurrence in steroid group, whereas 100% (2/2) in surgery group showed recurrence, suggested steroid therapy as first choice of treatment in GLM. Added to that, our study show no recurrence in the combined management group (steroid + surgery) compared to 40% recurrence in the surgery only group.

However a meta-analysis was performed to investigate the differences in the recurrence rate of conservative and surgical treatment using a random effects model with a total of 10 studies involving 1,101 patients were included demonstrated that there was no significant difference in the recurrence rate among patients who were treated by nonsurgical therapy and surgical treatment (Zhou et al., 2020). So we can conclude that further randomized controlled trials with larger group of patients from multiple centers with longer follow-up periods will be required to confirm the advantages of each approach.

## 5. CONCLUSION

Systemic steroid therapy with surgical resection is the recommended as first-line treatment strategy for IGM as it shows less recurrence rate and surgical scarring. Increased awareness of IGM will increase their understanding and improve their management.

### Limitation of the study

Limited number of cases due to being a rare disease, multicenter studies with longer duration may be helpful.



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**Author Contributions**

This work was carried out in collaboration between all authors. Conceptualized and designed the study, Drafted the initial manuscript, Reviewed and revised the manuscript, Coordinated and supervised data collection, critically reviewed the manuscript for important intellectual content.

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This study has not received any external funding.

**Conflict of Interest**

The authors declare that there are no conflicts of interests.

**Informed consent**

Written & Oral informed consent was obtained from all individual participants included in the study.

**Ethical approval**

The study was approved by the Medical Ethics Committee of Department of General Surgery, Faculty of Medicine, Ain shams University, Cairo, Egypt Code (IRB 00006379).

**Data and materials availability**

All data associated with this study are present in the paper.

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